PATENT COOPERATION TREATY



INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SCB63535WO00	FOR FURTHER ACTION See Form PCT/IPEA/416						
International application No. PCT/GB2004/002893	International filing date (da 06.07.2004	ny/month/year)	Priority date (day/month/year) 07.07.2003				
International Patent Classification (IPC) or national classification and IPC A61M15/00, A61K9/00, A61K31/135, A61K31/485							
Applicant GW PHARMA LIMITED et al.							
	 This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 						
2. This REPORT consists of a total o	f 7 sheets, including this	cover sheet.					
3. This report is also accompanied by	y ANNEXES, comprising:						
a. 🛭 sent to the applicant and to	the International Bureau)) a total of 3 sheets, a	as follows:				
and/or sheets containin	sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).						
☐ sheets which supersed beyond the disclosure supplemental Box.	sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the						
b. (sent to the International Busequence listing and/or table Box Relating to Sequence I	les related thereto, in com	nputer readable form o	of electronic carrier(s)) , containing a nly, as indicated in the Supplemental structions).				
4. This report contains indications rel	4. This report contains indications relating to the following items:						
Box No. I Basis of the opin	ion						
☐ Box No. II Priority							
Box No. III Non-establishme	ent of opinion with regard	to novelty, inventive st	ep and industrial applicability				
Box No. IV Lack of unity of i	nvention						
Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement							
☐ Box No. VI Certain documer							
	n the international applica						
☐ Box No. VIII Certain observat	ions on the international a	application					
Date of submission of the demand	D	Date of completion of this	report				
06.05.2005	o	9.09.2005					
Name and mailing address of the international	A Is	authorized Officer	nes Patenta				
preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 52365 Fax: +49 89 2399 - 4465	66 epmu d	/änttinen, H elephone No. +49 89 239	99-7442				

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/GB2004/002893

		<u> </u>
	Box No. I	Basis of the report
1.	. With regard filed, unles	d to the language , this report is based on the international application in the language in which it was otherwise indicated under this item.
	☐ This re which	eport is based on translations from the original language into the following language , is the language of a translation furnished for the purposes of:
	□ put	ernational search (under Rules 12.3 and 23.1(b)) Dication of the international application (under Rule 12.4) Ernational preliminary examination (under Rules 55.2 and/or 55.3)
2.	have been	If to the elements* of the international application, this report is based on <i>(replacement sheets which furnished to the receiving Office in response to an invitation under Article 14 are referred to in this priginally filed" and are not annexed to this report):</i>
	Description	, Pages
	1-24	as originally filed
	Claims, Nur	nbers
	1-22	received on 06.05.2005 with letter of 04.05.2005
	Drawings, S	heets
	1/7-7/7	as originally filed
	□ a sequ	ence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3.		nendments have resulted in the cancellation of:
		description, pages claims, Nos.
		drawings, sheets/figs sequence listing <i>(specify)</i> :
	☐ any	table(s) related to sequence listing (specify):
4.	had not bee	port has been established as if (some of) the amendments annexed to this report and listed below made, since they have been considered to go beyond the disclosure as filed, as indicated in the all Box (Rule 70.2(c)).
		description, pages claims, Nos.
	☐ the o	drawings, sheets/figs
		sequence listing (specify): table(s) related to sequence listing (specify):
	* If ite	m 4 applies, some or all of these sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/GB2004/002893

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	_	Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability				
1.	The	The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non- obvious), or to be industrially applicable have not been examined in respect of:				
		the entire international application,				
	Ø	claims Nos. 17-21				
		because:	se:			
	⊠	the said international application, or the said claims Nos. 18-21 relate to the following subject matter which does not require an international preliminary examination (specify):				
		see separate sheet				
	☒	the description, claims or drawi unclear that no meaningful opin	ngs nion ((indicate particular elements below) or said claims Nos. 17 are so could be formed (specify):		
		see separate sheet				
		the claims, or said claims Nos. could be formed.	are s	so inadequately supported by the description that no meaningful opinion		
	\boxtimes	no international search report h	as b	een established for the said claims Nos. 17-21		
		the nucleotide and/or amino aci C of the Administrative Instructi	d se ons	quence listing does not comply with the standard provided for in Annex in that:		
		the written form		has not been furnished		
				does not comply with the standard		
		the computer readable form		has not been furnished		
				does not comply with the standard		
		the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.				
		See separate sheet for further o	letail	ls		

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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_		· Al- N/ 1 1 4 1 4 1				
_		x No. IV Lack of unity of in	rventio	n		
1.	Ø	In response to the invitation ☐ restricted the claims. ☐ paid additional fees. ☐ paid additional fees under			additional fees, the applicant has:	
		neither restricted nor paid	d additio	onal fees.		
2.		☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.				
3.	This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is					
		complied with.				
		not complied with for the follo	owing r	easons:		
4.	. Consequently, this report has been established in respect of the following parts of the international application:					
	⊠	all parts.				
		the parts relating to claims N	os			
		para para tanàna dia mandra				
	Pay	No. V Reasoned stateme		A	05(0)	
_		licability; citations and exp	lanatio	ns suppor	35(2) with regard to novelty, inventive step or industrial ting such statement	
1.	Stat	tement				
	Nov	relty (N)	Yes: No:	Claims Claims	1-16,22	
	Inve	entive step (IS)	Yes: No:	Claims Claims	1-16,22	
	Indu	strial applicability (IA)	Yes: No:	Claims Claims	1-16,22	
2.	Cita	tions and explanations (Rule	70.7):			
	see	separate sheet				
	_					
	Box No. VII Certain defects in the international application					
The	The following defects in the form or contents of the international application have been noted:					

Form PCT/IPEA/409 (January 2004)

see separate sheet



INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

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1 Concerning Item III

- 1.1 It is unclear which technical features form the subject-matter of claim 17, because claims 9-12 relate to a dispenser and claim 17 refers to a formulation of said claims. Consequently and because said claim has not been searched, it cannot be examined in respect of Article 33(2)-(4) PCT.
- 1.2 Claims 18-21 fall under Rule 67.1(iv), because they concern a method for treatment of the human or animal body by therapy. Consequently and because said claims have not been searched, they cannot be examined in respect of Article 33(2)-(4) PCT.

2 Concerning Item V

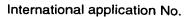
- 2.1 WO-A-02/32487 (D2) discloses a dispenser according to claim 1 without a mention about a "drug of abuse" contained in the reservoir. EP-A-0 672 416 (D3), WO-A-03/037306 (D4) and US-A-3 980 766 (D5) disclose that opiates and especially diamorphine or methadone may be advantageously administered orally. In the light of the combined teachings of D2 and D3, D4 or D5, it would be obvious for the skilled person to arrive at the subject-matter of claims 1-8. Thus, the subject-matters of claims 1-8 do not meet the requirement of Article 33(3) PCT.
- 2.2 In addition, the technical features and method steps of claims 14-16 and 22 are considered to be obvious from the combination of D2 and D3, the technical features of claims 9 and 10 from the combination of D2 and D4, and the technical features of claims 11-13 appear to relate merely to one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed. Consequently, said claims do not meet the requirement of Article 33(3) PCT.
- 2.3 Furthermore, for the entrance into the regional phase the attention of the applicant is drawn to WO-A-03/070304 (D1) which appears to disclose the subject-matters of claims 1-3, 7, 14-16 and 22 and has a priority date which is prior to the priority date of the present application.



INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

International application No.

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2.4 The industrial applicability (Article 33(4) PCT) of a device according to the claims 16 and 22 appears to be self-evident.

3 Concerning Item VII

The closest prior art has not been identified as required by Rule 5(a)(ii) PCT. Furthermore, the independent claims are not in the two-part form as required by Rule 6.3(b) PCT. In addition, the claims do not include reference signs in parentheses as required by Rule 6.2(b) PCT.





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CLAIMS

- 1. A dispenser comprising a reservoir containing a plurality of dosage units each of which comprise a formulation of a controlled drug or drug of abuse, said dosage units being contained in a tamper-evident manner such that access to the dosage units in use is controlled either by the dispenser or remotely and/or is monitored either by the dispenser or remotely.
- 2. The dispenser as claimed in claim 1, wherein the controlled drug or drug of abuse is a class A drug in a non-intravenous formulation, as defined by The Misuse of Drugs Act 1971.
- 3. The dispenser as claimed in claim 1 or 2, wherein the controlled drug or drug of abuse is an opioid.
- 4. The dispenser as claimed in any one of the preceding claims, wherein the opioid is methadone or a pharmaceutically acceptable salt or derivative thereof.
- 5. The dispenser as claimed in claim 4, wherein the opioid is methadone hydrochloride.
- 6. The dispenser as claimed in claim 4 or claim 5, wherein the formulation is for oral delivery.
- 7. The dispenser as claimed in any one of claims 1 to
- 3, wherein the opioid is diamorphine or a pharmaceutically acceptable salt or derivative thereof.
- 8. The dispenser as claimed in claim 7, wherein the opioid is diamorphine hydrochloride.







- 9. The dispenser as claimed in claim 7 or 8, wherein the formulation is dry and suitable for nasal delivery upon mixing with an aqueous solution.
- 10. The dispenser as claimed in claim 9, wherein the formulation further comprises a solubility enhancer.
- 11. The dispenser as claimed in claim 10, wherein the solubility enhancer is one or more of caffeine, sodium benzoate and sodium salicylate.
- 12. The dispenser as claimed in claim 10 or claim 11, wherein the solubility enhancer comprises caffeine and sodium benzoate and / or sodium salicylate.
- 13. The dispenser as claimed in any one of claims 9 to 12, wherein said formulation is a freeze-dried formulation.
- 14. The dispenser as claimed in any preceding claim, wherein more than 1 day's supply of dosage units are contained in the dispenser.
- 15. A reservoir as claimed in any one of claims 1 to 14, for use in the dispenser of claim 1.
- 16. A method of making a dispenser as defined in any one of claims 1 to 15, comprising introducing the plurality of dosage units into the reservoir and then sealing the reservoir in the dispenser so as to render the dispenser tamper-evident.







- 17. A formulation as defined in any one of claims 9 to 12.
- 18. A controlled method of taking a drug of abuse or a controlled drug comprising administering said drug of abuse or controlled drug from a dispenser as defined in any one of claims 1 to 14.
- 19. A method as claimed in claim 18, wherein said drug of abuse or controlled drug is present in a formulation as defined in any one of claims 9 to 12.
- 20. Use of a drug of abuse or a controlled drug in the manufacture of a medicament for use in a controlled method of taking a drug of abuse or controlled drug comprising administering said drug of abuse or controlled drug from a dispenser as defined in any one of claims 1 to 14.
- 21. Use as claimed in claim 20, wherein said drug of abuse or controlled drug is present in a formulation as defined in any one of 9 to 12.
- 22. A kit of parts comprising a dispenser as claimed in any one of claims 9 to 12; and aqueous liquid for introduction into the dispenser for rendering the formulation suitable for nasal administration.

633366; NLW; NLW

